Health Canada
Santé Canada

Health Products and Food Branch
Direction générale des produits de santé et des aliments

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Richard H. Carmona, M.D., M.P.H., F.A.C.S.
VADM, USPHS
United States Surgeon General
Chairman, Secretary's Task Force on Importation
5600 Fishers Lane, Room 18-67
Rockville, MD 20857

Dear Dr. Carmona:

Please find attached Health Canada's input to the Public Docket for the Health and Human Services Task Force on Drug Importation (docket number and title: 2004N-0115 - Prescription Drug Importation; Public Meeting). I trust that you will find this information helpful.

Yours sincerely,

D.C. Gorman

Diane C. Gorman
Assistant Deputy Minister

Enclosure: (1)

Canada

May 31, 2004

Input from Health Canada to the

Public Docket for the United States Department of Health and Human Services

Task Force on Drug Importation

I welcome the opportunity to provide the Health and Human Services' Task Force on Drug Importation with information pertaining to the regulatory mandate of Health Canada in relation to drugs, medical devices, and other therapeutic products in Canada. Health Canada trusts that this information will be helpful to the Task Force's deliberations.

Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. Health Canada regulates therapeutic products in accordance with Canada's *Food and Drugs Act* and its *Regulations*, and does so based on the premise that each country is responsible for the safety of products made available to its citizens.

Health Canada has a rigorous system for the regulation of therapeutic products comprised of three main components: pre-market review to determine if the product meets the legislative and regulatory requirements; post-market surveillance to monitor the safety and therapeutic effectiveness of the product; and inspection to verify compliance with the *Food and Drugs Act* and its *Regulations*. Drugs imported for sale in Canada, or for subsequent export, must first be approved by Health Canada and meet the requirements of Canada's *Food and Drugs Act* and *Regulations*. Through these activities, Health Canada ensures the products intended for Canadians are safe, efficacious and of high quality.

Health Canada works with a number of partners in protecting the health and safety of Canadians, including the provincial and territorial regulatory authorities for the practice of pharmacy and medicine, the Royal Canadian Mounted Police, and the Canada Border Services Agency (with respect to imports). Health Canada also works closely with foreign regulatory authorities, including the United States Food and Drug Administration, on shared public health and regulatory issues. This information-sharing and collaboration allows Canada and its regulatory partners to benefit from respective areas of expertise and knowledge, share information pertinent to regulatory issues such as product review, safety monitoring and compliance, and ensure that our respective regulatory practices are consistent with international norms.

Health Canada's Regulatory Responsibilities for Drugs and Other Therapeutic Products

The *Food and Drugs Act* and *Regulations* prohibit the sale of a drug unless it has been subject to pre-market safety, efficacy and quality review. In drug submissions, a manufacturer must present substantive scientific evidence supporting the information submitted to Health Canada as required by the *Food and Drugs Act* and *Regulations*. Pre-market submissions are reviewed by scientists at Health Canada to determine if the benefits outweigh the risks and the risks can be

mitigated. If the evidence shows the product meets the requirements stated in the *Act*, the product is issued a market authorization, and if applicable, a Notice of Compliance (NOC), which permit the sponsor to market the drug in Canada. In addition, the fabrication, packaging/labelling, importation, distribution, wholesaling and testing of such products are also monitored following the product's approval through an Establishment License framework.

Once a product is on the market in Canada, it is monitored for safety as well as its therapeutic effectiveness. Post-marketing activities include monitoring and collecting adverse reaction and medication incident data; reviewing and analysing marketed health product safety data; conducting risk/benefit assessments of marketed health products; and communicating product related risks to health care professionals and the public.

Establishment Licences are required for all Canadian businesses engaged in the fabrication, packaging/labelling, importation, distribution, wholesaling and testing of drugs in Canada. Before granting an Establishment Licence, Health Canada conducts an inspection to assess an establishment's compliance with the regulatory requirements applicable to the establishments' activity including those relating to Good Manufacturing Practices (GMPs). An Establishment Licence is granted only if the establishment complies with the requirements of the *Food and Drugs Act* and *Regulations*. Establishment Licences, issued by Health Canada, are renewed on a yearly basis. Establishment licence holders are inspected every three years.

Canada's *Food and Drug Regulations* also require that certain drugs, listed in a schedule to the *Regulations*, only be sold to a patient when a supporting prescription has been issued by a practitioner licensed to practice in a province of Canada. In Canada, provincial and territorial governments license and regulate doctors and pharmacists practising medicine and pharmacy through provincial colleges or registrars of physicians and pharmacists.

Importing Drugs and other Therapeutic Products into Canada

Drugs imported for sale in Canada, or for subsequent export, must first be approved by Health Canada and meet the requirements of Canada's *Food and Drugs Act* and *Regulations*. Such drugs must, for example be properly labelled with a valid Drug Identification Number (DIN) and be fabricated at a site compliant with Canada's GMP regulatory requirements. Health Canada, in partnership with Canada Border Services Agency, enforces the requirements that only drugs approved for use in Canada enter Canada. Establishments importing drugs for sale in Canada or for further export are also required to hold an Establishment Licence authorizing such import activities.

To determine whether drugs being brought into the country meet Canada's GMP regulatory requirements under the *Food and Drugs Act,* Health Canada uses reports from its own inspectors or from recognized partner countries under the terms of Mutual Recognition Agreements (MRAs) and the Pharmaceutical Inspection Cooperation Scheme (PIC/S). Health Canada also

uses inspection reports from the United States Food and Drug Administration. The use of inspection reports from recognized partner countries through MRAs or PIC/S is based on a rigorous process that has established equivalency of both GMP standards and compliance inspection procedures and reports between Canada and the partner country.

Canada has determined, through evaluation and experience, that MRA and PIC/S countries provide indication of GMP compliance equivalency that warrant their use. Canada has established MRAs with Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom. An MRA is also being finalized with Australia. The Pharmaceutical Inspection Cooperation Scheme members include the MRA countries listed above, as well as: Czech Republic, Hungary, Malaysia, Romania, Singapore, Slovak Republic and Latvia.

Exporting Drugs and other Therapeutic Products from Canada

Canada's *Food and Drugs Act* and *Regulations* operate to prohibit the export of drugs that are not approved for sale in Canada, as they do not distinguish between domestic and export sales. An exemption is, however, available to drug manufacturers who fabricate in Canada and sell a drug solely for export, who certify under oath that a product being exported complies with the laws of the country of import. This exemption avoids unnecessarily subjecting exporting manufacturers in Canada to Canada's *Food and Drugs Act* and *Regulations* when they have already complied with the laws of the importing country. It is important to reiterate that the exemption can only be used by drug manufacturers in Canada for drugs fabricated in Canada solely for export. This exemption cannot be used by pharmacists, other establishments, or individuals.

Compliance and Enforcement

Health Canada's Health Products and Food Branch has an Inspectorate which is tasked with verifying compliance with the *Food and Drugs Act* and *Regulations* and, where necessary, taking steps to enforce the prohibitions outlined in these laws.

Pursuant to their authority under the *Food and Drugs Act*, inspectors can enter and inspect places where therapeutic products are manufactured, prepared, preserved, packaged or stored in order to verify/monitor that Canada's food and drug laws are being complied with. If any non-compliance with federal laws is found, appropriate compliance and enforcement actions are taken.

Health Canada compliance and enforcement activities, with respect to therapeutic products, are conducted in concordance with the *Compliance and Enforcement Policy* of the Health Products and Food Branch. This policy stipulates that compliance and enforcement activities will be

guided by the level of risk to the health of Canadians and will be directed at the earliest point of distribution to achieve the greatest impact and efficiency. Compliance will normally be achieved through a cooperative approach between the regulated party and the Health Products and Food Branch Inspectorate and other relevant organisations within Health Canada. However, when this is not possible, a number of enforcement options may be used in an escalating fashion, including warning letters, seizures and detentions, formal hearings, or prosecution.

Conclusion

The regulation of drug safety worldwide is based on the premise that each country is responsible for the safety of products made available to its citizens. Health Canada contributes to maintaining and improving the health of Canadians by ensuring that drugs and other therapeutic products sold in Canada are safe, of high quality and therapeutically effective in accordance with their labelling, and with partners and stakeholders, are appropriately used and accessible in a timely and cost-effective fashion.

Diane C. Gorman
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Health Products and Food Branch
Health Canada